

Accelerating the Pace of Chemical Risk Assessments Workshop

September 14 – 15, 2016

U.S. Environmental Protection Agency

William Jefferson Clinton East Building, Room 1153 (“Map Room”)

1201 Constitution Avenue NW, Washington DC

Agenda

PURPOSE: The advent of new alternative methods (NAMs) for generating safety information on chemicals provides an opportune time to take stock of what chemical risk assessments could/should look like in the 21st century. A workshop is being convened comprising key international regulatory agencies and their science support colleagues to discuss progress in applying the new tools to prioritization, screening, and quantitative risk assessment (RAs) of differing levels of complexity. To date, most progress in applying NAMs has been in screening and prioritization, but ultimately to modernize quantitative risk assessment, there is a need to demonstrate how the data and tools can be incorporated into future RAs, in particular for data poor chemicals. Scientific and regulatory needs for the quantitative application of NAMs to RAs will be identified, and example case studies designed to address them will be explored. The case studies will be conducted by multinational groups, including the OECD, following the workshop.

DESIRED OUTCOMES:

- Common understanding of current state of the science applications of New Approach Methods (NAMs), including the regulatory context and presentation of practical examples
- Compilation of a master list of chemicals of common international interest for ongoing and future NAM application
- Identification of potential sources of NAM information and how such information could be shared and exploited.
- Commitment to development and sharing of case studies of mutual interest

WORKSHOP HOSTS:

Jim Jones, Assistant Administrator, US EPA Office of Chemical Safety and Pollution Prevention (OCSPP)

Thomas A. Burke, Deputy Assistant Administrator, US EPA Office of Research and Development (ORD)

VENUE: US Environmental Protection Agency, Room 1153, William J Clinton East Building, 12th and Constitution Avenue NW, Washington DC

DAY 1 – WEDNESDAY, SEPTEMBER 14, 2016

8:30 am **Registration**
9:00 am **Welcome**
Thomas A. Burke, PhD, MPH
Deputy Assistant Administrator, Office of Research and Development
US EPA

Jim Jones
Assistant Administrator, Office of Chemical Safety and Pollution Prevention
US EPA

Robert J. Kavlock, PhD
Deputy Assistant Administrator, Office of Research and Development
US EPA

9:30 am **Introductions**
Tour of the tables

Experiences of Participating Organizations

10:00am **The NICNAS Inventory Multi-tiered Assessment and Prioritisation (IMAP) Program**
Kerry Nugent, PhD
National Industrial Chemicals Notification and Assessment Scheme
Australia

10:30am **New Approach Methodologies to Support Canada's Chemicals Management Plan**
Tara Barton-Maclaren, PhD
Health Canada
Canada

11:00am **REACH and CLP and the Use of New Approach Methods Information**
Mike Rasenberg
European Chemical Agency (ECHA)
European Union

11:30am **Connecting Exposure, Toxicokinetics and Toxicity: Towards Animal Free Risk Assessment in Food Safety?**
Jean-Lou Dorne, PhD
European Food Safety Authority
European Union

12:00pm **Computational Risk Assessment for Mixtures of Chemicals: The Case of Aromatase Inhibitors**
Philippe Hubert, PhD
INERIS
France

12:15pm **LUNCH** (catered)

- 1:15pm** **Percellome Project with Special Reference to the Concept of "Signal Toxicity": Single Exposure Studies and a Newly Designed Repeated Dose Studies Introducing Baseline Responses and Transient Responses with Possible Link to Epigenetics**
Jun Kanno, MD, PhD
Japan Bioassay Research Center
- List of Chemicals in the Ministry of the Environment, Japan Progress of EXTEND2010. Results of Tier-1 Screening Assays for Candidate Substances, Aspect and Issues for Tier-1 Assessment and Tier-2 Testing**
Taisen Iguchi, PhD
Yokohama City University
- 1:45pm** **Integrated Risk Assessment Methodology for Endocrine Disrupting Chemicals (IRAMe)**
Kiyoun Lee, ScD, CIH
Seoul National University, Korea
- 2:15pm** **Current Chemical Management and Prioritization in Taiwan**
Steve Lin, PhD
Safety and Health Technology Center (SAHTECH), Taiwan
- 2:30pm** **Introduction to Agency for Science, Technology, and Research (A*STAR)**
Kenneth Lee, PhD
Agency for Science, Technology & Research (A*STAR), Singapore
- 2:45pm** **Integrated Approaches to Testing and Assessment (IATA) Case Studies Project**
Robert Diderich
Organisation for Economic Cooperation and Development (OECD)
- 3:15pm** **BREAK**
- 3:45pm** **The Frank R. Lautenberg Chemical Safety for the 21st Century Act**
Jeff Morris
Office of Chemical Safety and Pollution Prevention (OCSPP), US EPA
- 4:15pm** **Case Example for Use of High Throughput and Computational Approaches in Decision Making for Endocrine Disruption Potential**
Stanley Barone, PhD
Office of Chemical Safety and Pollution Prevention (OCSPP), US EPA
- 4:45pm** **California's Approach to Evaluating and Incorporating New Methods in Prioritization and Risk Assessment**
Gina Solomon, MD, MPH
California Environmental Protection Agency (CalEPA)
- 5:15pm** **Closing and Considerations for Tomorrow**
Robert J. Kavlock, PhD, US EPA
- 5:30pm** **Adjourn**
- 6:00 pm** **Group Dinner at Old Ebbitt Grill (separate checks)**
675 15th Street NW, Washington, DC

DAY 2 – THURSDAY, SEPTEMBER 15, 2016

9:00 am	Review of Activities of Day 1 Robert J. Kavlock, PhD, US EPA
9:15 am	Use of All Available Data in Accelerated Chemicals Assessment John R. Bucher, PhD Associate Director, National Toxicology Program National Institute of Environmental Health Sciences (NIEHS)
9:45am	Development of the RapidTox Decision Support Tool for 21st Century Chemical Risk Assessment Russell S. Thomas, PhD Director, National Center for Computational Toxicology Office of Research and Development (ORD) US EPA
10:15am	BREAK
10:30am	Facilitated Discussion: What Do Regulators Need to Accelerate Risk Assessment? Co-Chairs: Stanley Barone, PhD, US EPA, and Maurice Whelan, PhD, European Commission JRC Presentation: Mike Rasenberg, EChA
12:15pm	LUNCH
1:15pm	Facilitated Discussion: What Are the Chemicals of Common Interest Internationally? Co-Chairs: Tala Henry, PhD, US EPA, and Kerry Nugent, PhD, NICNAS Presentation: Matthew Gagné, Health Canada
2:30pm	Facilitated Discussion: How Do We Develop Shared Case Studies to Address the Challenges? Co-Chairs: Tina Bahadori, ScD, US EPA, and Kenneth Lee, PhD, A*STAR
4:30 pm	Agreement on All Action Items, Timeline, and Leads Co-Chairs: Robert J. Kavlock, PhD, US EPA, and Jeff Morris, US EPA
5:00 pm	Summary/Close Robert J. Kavlock, PhD, US EPA